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ASSESSING THE QUALITY OF LIFE IN A SPANISH POPULATION WITH MULTIPLE SCLEROSIS: THE SLIMS STUDY

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Symptoms of Multiple Sclerosis (MS) are related to a progressive and strong impact on patient's quality of life (QoL). PRIMUS questionnaire is a MS-specific-instrument to assess QoL. **OBJECTIVES:** To assess QoL in MS patients using the PRIMUS questionnaire and the relationships between QoL, disease duration and EDSS disability. **MATERIAL AND METHODS:** Non-interventional, cross-sectional and multicenter study. A total of 261 patients, >17 years with relapsing-remitting or secondary-progressive MS (RRMS/SPMS), treated with interferon beta-1b (≥6 months). PRIMUS questionnaire has three subscales: symptoms, activity limitations and QoL. For the present study, self-assessed changes were evaluated for QoL (0-22 score) and activity limitation (0-38 score) subscales. The higher scores the better QoL and the greater activity limitation. Correlations between PRIMUS-QoL and EUROQoL-5D, and with visual analog scale (VAS) were evaluated using Spearman-coefficient (S). **RESULTS:** Mean (SD) age was 41.7(10.3) years (61.3% women), 83.9% were RRMS diagnosed. Mean time since diagnosis was 7.6±5.8 years, higher in SPMS (6.9 ±5.2 vs. 11.2±7.4, p<0.0001). Mean EDSS disability was 2.6±1.75 (5.1±1.3 SPMS vs. 2.1±1.4 RRMS, p<0.0001). PRIMUS-QoL was better in RRMS patients: 18.3±6.8 vs. 9.9±7.1 (p<0.0001), getting worse as time from diagnosis increased (p<0.01) and with patient's disability (18.8±6.6 in early stages [EDSS<3.5] and 8.4±6.3 in advanced ones [EDSS>5], p<0.0001). PRIMUS-activity showed a relationship between loss of activity with disease duration (p<0.0001) and patient's disability (p<0.0001). PRIMUS-QoL showed a strong negative correlation (S=-0.7869) with EUROQoL-5D (as higher EUROQoL scores indicate worse QoL) and positive correlation with the-VAS (S= 0.7272). PRIMUS-activity showed a very strong correlation (S=0.8179) with EUROQoL-5D as well as a strong negative correlation (S=-0.7571) with the VAS. **CONCLUSIONS:** The QoL of MS patients changes according to the disease types and disability levels, and it progressively worsens with disease duration. PRIMUS questionnaire has demonstrated to be a good tool for assessing QoL and activity in MS patients.

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A MEASURE OF CARER QUALITY OF LIFE IN PARKINSON'S DISEASE (PDQ-CARER): DEVELOPMENT AND VALIDATION OF A SUMMARY INDEX SCORE

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OBJECTIVES: The PDQ-Carer is a 29 item measure of health related quality of life for use with carers of people with Parkinson's disease. The original development of the instrument identified four sub domains measured by the instrument. This study examined the possibility that the four domains could reasonably be summed to also provide a single summary index score. **METHODS:** The PDQ-Carer was administered in a postal survey of patients and carers registered with local branches of the Parkinson's Disease Society of Great Britain. Data from the four dimensions of the PDQ-Carer was subjected to higher order factor analyses. This produced a single factor suggesting that a single index can be calculated from the measure. Content validity of the measure was assessed by correlating results with the 'General Health Perceptions' scale of the SF-36, a generic measure of health status. **RESULTS:** A total of 236 carer questionnaires were returned, a response rate of 60.9%. The mean age of the sample was 68.2 years (SD 9.49; range 25-89 years); 63.5% females, 21.3% males. Higher order principle components factor analysis produced one factor, accounting for 85.5% of the variance. Consequently it was decided that the scores of the four domains could be summed to produce a single index figure. The psychometric properties of this index were explored using reliability tests and tests of construct validity. The newly derived single index was found to be both internally reliable (alpha=0.94) and supported by construct validity (correlation with GHP =0.50, p<0.001). **CONCLUSIONS:** The analysis undertaken here indicates that data from the PDQ-Carer can be presented in summary form. The index will provide an overall indication of the impact of caring. Furthermore, the single index reduces the number of statistical comparisons, and hence the role of chance, when exploring data from the PDQ-Carer.

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EFFECTS OF BG-12 ON QUALITY OF LIFE IN RELAPSING–REMITTING MULTIPLE SCLEROSIS: FINDINGS FROM THE PHASE 3 CONFIRM STUDY

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OBJECTIVES: To report the impact of BG-12 (dimethyl fumarate) on patient health-related quality of life (HRQoL) in CONFIRM, a 2-year, placebo-controlled study of efficacy and safety of BG-12 in patients with relapsing–remitting multiple sclerosis (RRMS). **METHODS:** Patients aged 18–55 years with RRMS (McDonald criteria 2005) and Expanded Disability Status Scale score 0–5.0 were randomized 1:1:1:1 to oral BG-12 240 mg twice (BID) or three times daily (TID), placebo, or subcutaneous glatiramer acetate (GA) 20 mg/day (reference comparator arm). A Short Form (SF)-36 questionnaire was administered to assess health status and HRQoL on 8 multi-item 100-point scales at baseline, 24 weeks, 1 year and 2 years. These scores were used to calculate Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. In addition, patients' global impression of well-being was assessed at baseline and every 3 months using a 100-point visual analogue scale (VAS). Higher scores indicated better HRQoL. **RESULTS:** The intent-to-treat population comprised 1,417 patients. Mean PCS scores increased from baseline to 2 years with BG-12 BID (+0.49) and TID (+0.33) versus a decrease with placebo (−0.71), indicating significantly improved (BID)/a trend toward better (TID) physical health and well-being relative to placebo (p=0.0217 and p=0.0519, respectively). With GA, mean PCS score increased by 0.42 at 2 years (p=0.0259 versus placebo). SF-36 MCS scores showed similar trends but results were not statistically significant. Mean changes from baseline to 2 years in VAS scores were 0.3, −0.3 and 2.1 with BG-12 BID, TID and GA, respectively, versus −3.9 with placebo (p=0.0003, p=0.0025 and p<0.0001, respectively), indicating a significantly improved sense of well-being with active treatment. **CONCLUSIONS:** Together with the significant improvement in clinical and neuroradiological measures, benefits on patient-reported HRQoL further support the potential for BG-12 to become a valuable oral treatment option for patients with relapsing MS.

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CROSS-CULTURAL VALIDATION OF THE HUNTINGTON'S DISEASE QUALITY OF LIFE BATTERY FOR CARERS IN FRANCE AND ITALY

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OBJECTIVES: Huntington's disease (HD) is a neurodegenerative disease that causes movement disorders, and cognitive and psychological deterioration; leading to considerable burden for patients and their families. The paucity of research into the impact of HD on the quality of life (QoL) of family carers led Aubeeluck and Buchanan to develop and validate a disease-specific QoL measure to evaluate caregivers' QoL, and assess the efficacy of therapeutic interventions. This current study aimed to validate a shortened version of the HD QoL Battery for Carers (HDQoL-C) in France and Italy. **METHODS:** The shortened version of the HDQoL-C comprised two components: the satisfaction with life component (3 items) and the feelings about living with HD(17 items). It was translated forwards and backwards by native speakers. 301 family carers completed the questionnaire. While face validity was studied through item completion, internal validity was evaluated using factorial structure and internal consistency. Differential item functioning (DIF) analyses were also performed to test whether all items behaved in the same manner among the country subgroups. External validation was tested using known-group comparison analyses between three severity subgroups, according to dependence, global clinical severity and motor severity. **RESULTS:** The translated short version showed satisfactory face validity with few missing data (up to 6%) and a good reliability despite the item reduction (Cronbach's alpha coefficients of around 0.8 for both components). The factor analysis was comparable to the original version, with the variable distribution according to the two factors being the same. No significant DIF between France and Italy was detected. Carers who cared for patients with less clinically severe symptoms of HD reported significantly better QoL than carers of patients with more clinically severe symptoms. **CONCLUSIONS:** These findings indicate that the HDQoL-C is multi-lingual, multi-cultural and easily applicable in other languages.

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NON-DIABETIC PERIPHERAL NEUROPATHIC PAIN IS UNDERDIAGNOSED IN GP PRACTICES ALTHOUGH IT HAS HIGH IMPACT ON PATIENTS' HEALTH RELATED QUALITY OF LIFE

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OBJECTIVES: Peripheral neuropathic pain (PNP) is a complex type of pain initiated by a primary lesion or dysfunction in the nervous system and causes large impact on health related quality of life (HRQL). While PNP in diabetes is in focus much less attention is given to non-diabetic PNP. The main aims of present study were to screen patients in GP practices for non-diabetic PNP, assess their HRQL and explore key influential variables. **METHODS:** Non-diabetic patients aged ≥30 years were recruited in 10 general practices in Hungary. At first, patients filled in the PainDetect Questionnaire (PD-Q). Patients achieving ≥13 PD-Q score (unclear or possible neuropathic pain) were further assessed by DN4 (Neuropathic Pain Diagnostic Questionnaire). The cut-off value for the diagnosis of neuropathic pain in the DN4 is a total score of 4/10. Patients with PD-Q score >18 or DN4 score ≥4 were considered to be PNP patients. They completed the EQ-5D questionnaire and GPs provided demographic data. **RESULTS:** One hundred and eleven patients with non-diabetic PNP were selected. Among them there were more women (69%), mean age was 62 (SD=14) years. Only 15 (14%) patients have already had prior PNP diagnosis at inclusion. EQ-5D index showed 58% decrease compared to a perfect health state and 44% decrease to the gender and age matched Hungarian population (0.42 vs. 0.75, p<0.001). The pain/discomfort dimension was the most affected in the EQ-5D, 96% of patients reported some or serious problem. Similar ratios for mobility, self-care, usual activities and anxiety dimensions were 83%, 37%, 82% and 83%. Average (SD) EQ-5D score of patients with mild, moderate and severe average pain were 0.56 (0.29), 0.43 (0.29) and 0.29 (0.27). The differences were significant (p=0.014). **CONCLUSIONS:** Our research showed that non-diabetic neuropathic pain is poorly